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Scriptiformation™

Cortenema®

disposable unit-dose
hydrocortisone retention enema

COMPOSITION: Each 60 ml. unit contains Hydrocortisone, 100 mg., in an aqueous solution of carboxypolyethylene, polysorbate 80, and methylparaben, 0.18% as a preservative.

INDICATIONS: Adjunctive therapy in ulcerative colitis; especially distal ulcerative proctitis, proctosigmoiditis, left-sided colitis; proved useful also in some cases involving transverse and ascending colons.

CONTRAINDICATIONS: Systemic fungal infections; recent ileocolostomy.

WARNINGS: In severe ulcerative colitis, avoid delay of needed surgery pending response to medical therapy. Careful insertion of enema tip is advisable to avoid rectal wall damage. Observe warnings of corticosteroid use; increase dosage of rapid-acting corticosteroids in unusual stress; corticosteroids may mask and decrease resistance to infection; prolonged use may predispose to cataracts, glaucoma, secondary ocular infections.

Usage in pregnancy: Pending adequate studies, corticosteroid use in pregnant, lactating or potentially childbearing women requires weighing possible drug benefits against potential hazards to mother and progeny. After large corticosteroid doses during pregnancy, observe neonates for hypoadrenalism.

Hydrocortisone or cortisone therapy may increase blood pressure, sodium and water retention, potassium excretion—effects less likely with synthetic derivatives, except in high doses. Salt restriction and potassium supplementation may be needed. All corticosteroids increase calcium excretion.

Avoid immunization procedures, including smallpox vaccination, during corticosteroid therapy, because of possible neurologic complications and lack of antibody response. Observe corticosteroid-treated patients with latent tuberculosis or tuberculin reactivity for signs of reactivated disease; provide chemoprophylaxis during prolonged corticosteroid dosage.

PRECAUTIONS: Use CORTENEMA cautiously in probability of bowel perforation, abscess or pyogenic infection, open anastomoses, obstruction, extensive fistulas or sinus tracts, and in peptic ulcer, diverticulitis, renal insufficiency, hypertension, osteoporosis and myasthenia gravis. Minimize hazard of adrenal cortical insufficiency after prolonged treatment, by reducing dosage gradually and by adding mineralocorticoid and glucocorticoid support in post-treatment stress situations. In surgical infections during corticosteroid therapy, consider increasing antimicrobial dosage.

Use corticosteroids cautiously in hypothyroidism, cirrhosis and ocular herpes simplex; use aspirin cautiously with corticosteroids in hypoprothrombinemia. Psychic derangements may appear and emotional instability or psychotic tendencies may be aggravated with corticosteroid use. Carefully monitor growth of children on long-term corticosteroid therapy. Use the lowest effective corticosteroid dosage and reduce it gradually when possible.

ADVERSE REACTIONS: Local pain or burning, and rectal bleeding attributed to CORTENEMA have been reported rarely. Apparent exacerbations or sensitivity reactions also occur rarely. The following adverse reactions should be kept in mind whenever corticosteroids are given by rectal administration:

Fluid and Electrolyte Disturbances: Sodium retention; fluid retention; congestive heart failure in susceptible patients; potassium loss; hypokalemic alkalosis; hypertension. **Musculoskeletal:** Muscle Weakness; steroid myopathy; loss of muscle mass; osteoporosis; vertebral compression fractures; aseptic necrosis of femoral and humeral heads; pathologic fracture of long bones. **Gastrointestinal:** Peptic ulcer with possible perforation and hemorrhage; pancreatitis; abdominal distention; ulcerative esophagitis. **Dermatologic:** Impaired wound healing; thin fragile skin; petechiae and ecchymoses; facial erythema; increased sweating; may suppress reactions to skin tests. **Neurologic:** Convulsions; increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment; vertigo; headache. **Endocrine:** Menstrual irregularities; development of Cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness; decreased carbohydrate tolerance; manifestations of latent diabetes mellitus; increased requirements for insulin or oral hypoglycemic agents in diabetics. **Ophthalmic:** Posterior subcapsular cataracts; increased intraocular pressure; glaucoma; exophthalmos.

Metabolic: Negative nitrogen balance due to protein catabolism. **DOSEAGE AND ADMINISTRATION:** CORTENEMA should be used adjunctively with such supportive measures as dietary control, sedatives, antidiarrheal and antibacterial agents and blood replacement. The usual dosage, administered intrarectally in the evening before retiring, is 1 CORTENEMA per day for 2-3 weeks and every other evening thereafter until clinical and proctologic remission occur. CORTENEMA should be retained at least 1 hour or, preferably, all night and may be facilitated by prior sedative or antidiarrheal medication. Duration of treatment depends on both clinical and proctologic response. Clinical symptoms usually subside within 3-5 days; mucosal improvement may require longer, up to 2-3 months. Discontinue CORTENEMA if improvement fails to occur within 3 weeks.

HOW SUPPLIED: Single-dose 60-cc. bottles, in packages of 1 or 7, with instructions for patients.



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